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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,996	02/18/2005	Hiroyuki Asada	05105/HG	3212
1933 7590 07/16/2007 FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 220 Fifth Avenue 16TH Floor NEW YORK, NY 10001-7708			EXAMINER WEBB, WALTER E	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,996

Applicant(s)

ASADA ET AL.

Examiner

Walter E. Webb

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :09/20/2005, 05/17/2005, 02/18/2005.

DETAILED ACTION

Status of Claims

Claims 1-4 are pending.

Claims 1-4 are rejected.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider et al. (US 6,011,062).

3. Schneider et al. teach an ophthalmic solution comprising a prostaglandin at 0.001 to 0.005% at pH 6 +/- 0.2. (See col. 9, Example 2 (table).) (Schneider teaches that latanoprost can be used in that invention in column 5, line 57.)

Claims 1 and 2 of applicant's invention encompasses the example taught in Schneider et al., and have therefore been anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (US 6,011,062) as applied to claims 1 and 2 above, and further in view of Inada et al. (US 5,916,550).

6. In claim 3, applicant claims the same concentration range for latanoprost as in claim 2, but adds epsilon-aminocaproic acid at a range of 0.1 to 2% (W/V). In claim 4, applicant specifies the latanoprost concentration is 0.005% (W/V) and epsilon-aminocaproic acid is 1% (W/V) (See col. 2, lines 10-15). Schneider et al. does not teach the epsilon-aminocaproic acid. However, Inada et al. teach an ophthalmic solution containing epsilon-aminocaproic acid at concentration of 0.002 to 2% (W/V). A person having ordinary skill in the art would appreciate having latanoprost at 0.005% and epsilon-aminocaproic acid at 1% given the fact that the prior art teaches a range that encompasses these concentrations.

7. At the time of applicant's invention, it would have been obvious to one having ordinary skill in the art to combine the latanoprost of Schneider with the epsilon-aminocaproic acid of Inada especially when both have been taught in the prior art as major ingredients in ophthalmic solutions.

8. No claims are allowed.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kararli et al. (US 20020035264) teach that drugs having utility as a topical ophthalmic application can be used in co-therapy, co-

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administration or co-formulation. Such drugs include latanoprost and aminocaproic acid. See para. 0350, pg. 15 of specification.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 272-1600. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


WW


JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER